

## REMARKS

Claims 1-10 and 18 are cancelled herein. Claims 11-12, 14-17, and 27-29 are amended herein. Claims 30-32 are newly added. Claims 11-17 and 19-32 are currently pending.

Claims 12, 14-16, and 27-28 are amended herein to correct various typographical errors and matters of form.

Claim 11 is amended herein to recite "wherein the polynucleotide comprises one or more oligonucleotides, each oligonucleotide comprising one or more copies of the NF- $\kappa$ B binding site decoy, wherein the polynucleotide decoy is delivered by a polymeric vector." Support for this amendment is found, for example, at paragraphs [0033] and [0147]-[0148] of the Specification as filed.

Claim 17 is amended herein to recite "comprising one or more copies of a NF- $\kappa$ B binding site, wherein the oligonucleotide decoy is delivered by a polymeric vector." Support for this amendment is found, for example, in Claim 18 as originally filed.

Claim 29 is amended herein to recite "comprising one or more copies of a NF- $\kappa$ B binding site, wherein the oligonucleotide decoy is complexed with a polymeric delivery vector." Support for this amendment is found, for example, at paragraphs [0033] and [0147]-[0148] of the Specification as filed.

Newly added Claims 30-32 are dependent from claims 11, 17, and 29, respectively, and recite the polymeric vector is selected from the group consisting of "polyhydroxylamidoamines, cyclodextrin-based dendritic macromolecules, 1,3-dipolar addition polymers, and carbohydrate-containing biodegradable polyesters." Support for these claims is found, for example, at paragraphs [0058]-[0088] of the Specification as filed.

It is believed that no new matter is added and that no additional claims fees are due. Accordingly, entry of the present Amendment is believed to be in order and is respectfully requested.

**Response to Restriction Requirement**

In the Office Action, the Examiner required restriction to one of the following groups of claims:

Group 1, claims 1, 2 and 4-7, drawn to double stranded concatemers containing at least two copies of sequence(s) that are repeated and act as transcription factor decoys.

Election of this Group requires further election of a single transcription factor selected from NF-κB, AP-1, ATF2, ATF3, and SP1.

Group 2, claims 1 and 3-7, drawn to double stranded concatemers containing at least two copies of sequence(s) that are different from each other and act as transcription factor decoys. Election of this Group requires further election of a pair of different transcription factors selected from NF-κB, AP-1, ATF2, ATF3, and SP1.

Group 3, claims 8-10, drawn to methods of delivering transcription factor decoys in vitro or in vivo, in isolated cells or intact animals, comprising administering a concatemerized double-stranded oligonucleotide molecule at least two end-to-end repeated copies of a nucleotide transcription factor may be NF-κB. Election of this group requires a further election of a physiological condition for reasons given below selected from developmental defects, aging, toxic exposure, myocardial ischemia/reperfusion and myocardial infarction, heart failure and hypertrophy, cardioprotection, stroke, neuroprotection, sepsis, arthritis, asthma, heritable inflammatory disorders, cancer, heritable immune dysfunctions, inflammatory processes caused by disease, inflammatory processes caused by injury, inflammatory processes caused by infection, oxidative stress caused by

disease, oxidative stress caused by surgery, oxidative stress caused by injury, oxidative stress caused by response to surgery, or oxidative stress caused by response to trauma.

Group 4, claims 11-29, drawn to a method for treatment of NF-κB-associated diseases which comprises administering to an animal an effective amount of a polynucleotide NF-κB chromosomal binding site decoy which antagonizes NF-κB-mediated transcription of a gene located downstream of a NF-κB binding site wherein the polynucleotide comprises one or more copy of the oligonucleotide decoy. Election of this group requires the further election of a single physiological condition selected from reperfusion disorder in ischemic disease, aggravation of a prognosis or an organ or aggravation of a prognosis of a heart transplantation or aggravation of a prognosis of an organ surgery, a post-PCTA restenosis, an inflammatory disease, an autoimmune disease, a cancer metastasis, a cancer invasion, cachexia, an immunological disorder, septic shock, transplant rejection, radiation damage, a reperfusion injury after ischemia, arteriosclerosis, a neurodegenerative disease, inhibition of cell death and apoptosis in ischemic-reperfused myocardium, inhibition of cell death and apoptosis in ischemic-reperfused brain, inhibition of apoptosis in congestive heart failure, inhibition of apoptosis in cardiomyopathy, or procedural vascular trauma.

Applicants hereby elect, without traverse, Group 4, including claims 11-17 and 19-32, drawn to a method for treatment of NF-κB-associated diseases which comprises administering to an animal an effective amount of a polynucleotide NF-κB chromosomal binding site decoy which antagonizes NF-κB-mediated transcription of a gene located downstream of a NF-κB binding site wherein the polynucleotide comprises one or more copy of the oligonucleotide decoy, wherein the oligonucleotide decoy is delivered by a polymeric vector.

With respect to the further restriction requirement of a single physiological condition, Applicants traverse the restriction requirement on the basis that the present invention is

distinguishable over Morishita, such that the special technical feature is a contribution over the prior art.

The Examiner has asserted that

the diseases and conditions listed above lack unity, because although all require the same special technical feature of administering an oligo decoy directed to a transcription factor to achieve amelioration of the condition, this is not considered to be a contribution over the prior art. For example, Morishita et al. teaches [ ] that the compositions can be used to treat inflammatory disorders such as atopic dermatitis, psoriasis, and ulcerative colitis.

By the present amendment, independent Claims 11, 17, and 29 are amended to include the limitation that the decoys are delivered by a polymeric vector. Claims 30-32 provide further limitations as to the polymeric vectors disclosed in the present Application and suitable for use in decoy delivery.

Applicants therefore submit that the special technical feature of the present invention further comprises delivery of the decoys by a polymeric vector. Morishita does not teach, *inter alia*, delivery of decoys via polymeric vector. Accordingly, Applicants submit the basis of the restriction requirement is overcome by the present amendment.

However, in order to provide a complete reply to the January 27, 2010 Office Action, Applicants provisionally elect with traverse the condition "reperfusion disorder in ischemic disease." Claims 11-15 read on the elected condition. Applicants further submit that claims 17, 23, 26, and 27 should be considered together with claims 11-15, since those claims each recite terms related to ischemia and reperfusion, such that a search of those claims would not present an undue additional search burden on the Examiner: Claims 17 and 23 recite "reperfusion injuries after ischemia"; Claims 26 and 27 recite "ischemic-reperfused myocardium" and "ischemic-reperfused brain," respectively. Applicants submit that a search of those key words would likely return the same prior art references as the elected

physiological condition. Hence, under the provisional election of "reperfusion disorder in ischemic disease," Applicants submit that Claims 17, 23, and 26-27 are properly considered together with Claims 11-15.

## **CONCLUSION**

It is believed that the above represents a complete response to the Office Action dated December January 27, 2010. Applicants therefore respectfully request that examination on the merits be commenced.

Respectfully submitted,

*/Jennifer L. Livingston/*  
Jennifer L. Livingston  
Reg. No. 56,404  
1900 Chemed Center  
255 East Fifth Street  
Cincinnati, OH 45202  
(513) 977-8359 (phone)  
(513) 977-8141 (fax)